IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

(1) TINA JOHNSON	§	
	§	
	§	
Plaintiff,	§	
	§	Case No.
VS.	§	
	§	
(1) TEVA PHARMACEUTICALS USA, INC	§	
(2) QUALITEST	§	
(3) WYETH, INC., d/b/a WYETH	§	
(4) SCHWARZ PHARMA, INC.	§	
(5) ALAVEN PHARMACEUTICALS, LLC.	§	JURY DEMAND
Defendants.		

ORIGINAL COMPLAINT

TO THE HONORABLE U.S. DISTRICT JUDGE:

NOW COMES Plaintiff, TINA JOHNSON, through undersigned counsel, and hereby submit this complaint Teva Pharmaceuticals USA, Inc., Qualitest, Wyeth, Inc., Schwarz Pharma and Alaven Pharmaceuticals, LLC.; hereinafter referred to as "Defendants," and respectfully represents to this Court the following:

1. PARTIES

1.01 Plaintiff, Tina Johnson (hereinafter referred to as "Mrs. Johnson"), is an individual who is a resident and citizen of the City of Sulphur, Calcasieu Parish, Louisiana.

1.02 Defendant TEVA PHARMACEUTICALS USA, INC. (hereinafter referred to as "Teva") is a Delaware Corporation with its principal place of business in Pennsylvania. References to Teva include Teva individually, and collectively all of its predecessors in interest and divisions. Defendant Teva and/or one of its predecessors in interest and/or one of its family of wholly owned divisions was engaged in the business of testing, developing, manufacturing,

labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, metoclopramide tablets in the State of Louisiana and in interstate commerce.

1.03 Defendant QUALITEST PHARMACEUTICALS, INC. (hereinafter referred to as "Qualitest") is an Alabama Corporation with its principal place of business in Huntsville, Alabama. Defendant Qualitest and/or one of its predecessors in interest and/or one of its family of wholly owned divisions was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, metoclopramide tablets in the State of Louisiana and in interstate commerce.

1.04 Defendant WYETH, Inc., d/b/a WYETH (hereinafter "WYETH"), was and is a Delaware corporation with its principal place of business at 500 Arcola Drive, Collegeville, Pennsylvania, and is the successor in interest to A.H. Robins Company, Inc., a Virginia corporation which first obtained approval by the Food and Drug Administration to distribute metoc1opramide, under the brand name of Reglan, in the United States.

1.05 Until December 27, 2001, WYETH Manufactured and distributed Reglan through its WYETH-Ayerst Laboratories Division in St. Davids, Pennsylvania. Metoclopramide is the active ingredient of Reglan. WYETH also manufactured and distributed generic metoc1opramide through its ownership of ESI LEDERLE, Inc., (ESI) which was formerly a subsidiary of WYETH and was merged into WYETH on December 15, 1998. On December 27, 2001, WYETH sold the rights and liabilities associated with Reglan tablets and Reglan syrup to SCHWARZ PHARMA, INC, a Delaware corporation with its principal place of business in Wisconsin.

1.06 References in this Complaint to WYETH include both WYETH, INC, individually and as successor in interest to A.H. ROBINS, INC and AMERICAN HOME PRODUCTS CORPORATION. At all times material hereto, WYETH was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, metoclopramide tablets in the State of Louisiana and in interstate commerce. WYETH is subject to the jurisdiction and venue of the US Court.

1.07 Defendant SCHWARZ PHARMA, INC., (hereinafter "SCHWARZ"), is a Delaware corporation duly qualified to do business in the State of Louisiana with its principal place of business in Mequon, Wisconsin. Defendant SCHWARZ and/or one of its predecessors in interest and/or one of its family of wholly owned divisions was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, metoclopramide tablets in the State of Louisiana and in interstate commerce. In February, 2008, Schwarz transferred its rights to Reglan tablets to Alaven Pharmaceuticals, LLC, a Georgia limited liability company with its principal place of business in Georgia.

1.08 Defendant ALAVEN PHARMACEUTICALS, LLC (hereinafter referred to as “Alaven”) is a Georgia limited liability corporation with its principle place of business in Marietta, Georgia. Defendant Alaven and/or one of its predecessors in interest and/or one of its family of wholly owned divisions was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, metoclopramide tablets in the State of Louisiana and in interstate commerce.

2. VENUE AND JURISDICTION

2.01 Both jurisdiction and venue are proper in the Western District of Louisiana. The Defendants conduct or have conducted business activity in Calcasieu Parish, Louisiana and the Defendants have distributed products throughout Calcasieu Parish. Mrs. Johnson was prescribed, purchased and consumed the Defendants' products in the Western District of Louisiana.

2.02 Jurisdiction is based on complete diversity between the Plaintiff and all of the Defendants pursuant to 28 U.S.C. § 1332.

2.03 Venue is proper as to causes of action against all Defendants because:

1. A substantial part of the cause of action accrued in the State of Louisiana in that Mrs. Johnson received and consumed the Defendants' pharmaceutical products in Calcasieu Parish, Louisiana and sustained injury in Calcasieu Parish, Louisiana.
2. All of the Defendants have directed their products into Calcasieu Parish, Louisiana.
3. All of the Defendants have sold their products in Calcasieu Parish,
4. Calcasieu Parish, Louisiana sits in the Western District of Louisiana.

2.04 The amount in controversy exceeds $75,000.00.

3. STATEMENT OF FACTS

A. Mrs. Johnson Developed Tardive Dyskinesia after Ingesting Reglan/metoclopramide

3.01 Plaintiff brings this action for the purpose of recovering damages for the personal injuries Mrs. Johnson has suffered as a result of being prescribed and ingesting Reglan, metoclopramide and/or metoclopramide HCl (hereinafter referred to as "Reglan/metoclopramide").

3.02 In July 2002, Mrs. Johnson's physician prescribed Reglan/metoclopramide at a dosage of 5 mg to treat stomach problems. Mrs. Johnson continued to take Reglan/metoclopramide through and until March 2009.

3.03 Reglan/metoclopramide is a drug that is used for treatment of gastroesophageal reflux disease (GERD), irritable bowel syndrome (IBS), and/or other gastrointestinal disorders by blocking dopamine receptors in the brain and throughout the body, thus enhancing movement or contractions of the esophagus, stomach and intestines.

3.04 Upon information and belief, in prescribing the Reglan/metoclopramide to Mrs. Johnson on a long-term basis, her prescribing doctor relied upon information published in the package inserts and/or the Physicians' Desk Reference (hereinafter referred to as "PDR") or otherwise disseminated by the Reference Listed Drug Company (hereinafter referred to as "RLD") and/or the New Drug Application Holder (hereinafter referred to as "NDA Holder").

3.05 Mrs. Johnson ingested the Reglan/metoclopramide as prescribed.

3.06 The Reglan/metoclopramide ingested by Mrs. Johnson was manufactured by Teva Pharmaceuticals USA, Inc. and Qualitest.

3.07 Mrs. Johnson used the pharmaceutical drugs Reglan/metoclopramide without substantial change in the condition of the drugs between the time of design and manufacture of the drugs and the time she used the drugs as directed.

3.08 Mrs. Johnson was not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated in the PDR and RLD product inserts, or by the NDA Holders and/or ANDA Holders.

3.09 Mrs. Johnson's use of Reglan/metoclopramide, as prescribed, resulted in

overexposure to the drugs which have caused her to suffer serious, permanent and disabling injuries, including but not limited to, injuries of or associated with the central nervous and extrapyramidal motor systems, specifically Tardive Dyskinesia, a severe and often permanent disfiguring neurological movement disorder.

3.10 Mrs. Johnson's tardive dyskinesia, caused by the ingestion of metoclopramide, is permanent.

3.11 Mrs. Johnson has experienced and will continue to experience medical and related expenses, loss of ability to provide household services, disfigurement, disability, pain, suffering, psychological injury and other injuries and damages due to the prescription and ingestion of this drug.

3.12 In February, 2009 the United States Food and Drug Administration (hereinafter referred to as "FDA") recognized the inadequate nature of Defendants' labels and warnings for Reglan and issued an advisory requiring the addition of a boxed warning. This new warning, explicitly states that "[p]rolonged treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases. . ." The FDA is also now requires that manufacturers/Defendants implement a Risk Evaluation and Mitigation Strategy because the FDA has determined that the use of Reglan/metoclopramide "pose[s] a serious and significant public health concern requiring the distribution of a Medication Guide." This Medication Guide, setting out all the risks of the drug and to be given to all users "is necessary for the patients' safe use of Reglan (metoclopramide). . ." Neither this Boxed Warning nor the Medication Guide was available to Mrs. Johnson or her physician.

B. Defendants' Wrongful Conduct

3.13 At all relevant times, Defendants were acting by and through their agents,

servants, and/or employees, each of whom were acting within the scope and course of their employment by agency or authority on their behalf.

3.14 At all times relevant hereto, Defendants were engaged in the business of testing, developing, manufacturing, labeling, marketing, delivering, distributing, promoting, and/or selling, either directly or indirectly, through third parties or related entities, metoclopramide tablets in the State of Louisiana and in interstate commerce.

3.15 Defendants marketed, manufactured and distributed Reglan/metoclopramide and encouraged the long term use of these drugs, misrepresented the effectiveness of these drugs and concealed the drug's dangerous side effects.

3.16 Reglan/metoclopramide is indicated only for use for no greater than 12 weeks; however, Defendants represented that Reglan/metoclopramide was safe for use to treat nausea and/or esophageal reflux for durations that exceed 12 weeks.

3.17 Patients who use Reglan/metoclopramide for long periods are at a significantly increased risk of developing severe and permanent neurological damage.

3.18 The serious side effects caused by prolonged exposure to Reglan/metoclopramide include, but are not limited to, central nervous system disorders, depression with suicidal ideation, akathisia, tardive dyskinesia, tardive dystonia, visual disturbances and interference with drug metabolism.

3.19 Tardive dyskinesia, one of the serious side effects associated with the ingestion of Reglan/metoclopramide is a debilitating neurological disorder that often results in involuntary and uncontrollable movements of the head, neck, face, arms, legs and trunk, in addition to facial grimacing, uncontrollable tongue movements and other involuntary movements. Presently, there is no cure for tardive dyskinesia.

3.20 Defendants have a duty to ensure their warnings to the medical community are accurate and adequate, to conduct safety surveillance of adverse events for the drug, and to report *any* data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug.

3.21 Defendants represented that Reglan/metoclopramide was safe for use to treat gastritis/gastroesophageal reflux knowing that the drug was not safe for that purpose and was dangerous to the health and body of Mrs. Johnson.

3.22 Defendants represented that Reglan/metoclopramide caused minimal side effects knowing that the drug caused central nervous system side effects, and extrapyramidal symptoms, among other side effects, far more frequently than represented.

3.23 Defendants had actual knowledge, either through their own studies or studies by independent investigators, that doctors frequently prescribed Reglan/metoclopramide for long-term use that was not safe for patients.

3.24 Defendants also had actual knowledge, through research by independent investigators, that the risk of tardive dyskinesia and other extrapyramidal side effects of Reglan/metoclopramide in patients who receive the drug for 12 weeks or longer is approximately 100 times greater than disclosed in package inserts and the PDR.

3.25 Defendants knew, or through the exercise of reasonable care should have known, that many patients who use Reglan/metoclopramide are not able to effectively metabolize it and that as a foreseeable consequence of their inability to effectively metabolize the drug, those patients have a greater risk of developing serious and permanent injuries.

3.26 Defendants had actual knowledge of facts which demonstrated that representations in the Reglan/metoclopramide package insert, the PDR and literature they

distributed to physicians were false and misleading.

3.27 Defendants failed to correct their monograph to include these facts and/or disclose that knowledge to the medical community, Plaintiff, and other foreseeable users.

3.28 Defendants, as prescription drug manufacturers and/or distributors, knew or should have known that so-called "drug product selection laws," enacted in every state, including Louisiana, authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limitations, with a generic drug product that is therapeutically equivalent to the name brand drug product.

3.29 Defendants disseminated to physicians, through package inserts, the publication of the PDR, and otherwise, information concerning the properties and effects of Reglan/metoclopramide, with the intention that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients.

3.30 Defendants knew, or should have known through the exercise of reasonable care, that the package insert for Reglan/metoclopramide substantially understated the prevalence and/or risk of acute and long-term side effects on ingesting Reglan/metoclopramide.

3.31 Defendants failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short-term and long-term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

3.32 Defendants owed a duty in all of their several undertakings, including the dissemination of information concerning Reglan/metoclopramide, to exercise reasonable care to ensure that they did not create unreasonable risks of personal injury to others.

3.33 Reglan/metoclopramide was widely advertised by Defendants as a safe and

effective treatment for diabetic gastroparesis, gastroesophageal reflux disease (GERD) and other gastrointestinal disorders.

3.34 Defendants failed to conduct and report post market safety surveillance on Reglan/metoclopramide.

3.35 Defendants failed to adequately review all adverse drug event information[1] and to report any information bearing upon the adequacy and accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan/metoclopramide.

3.36 Defendants failed to monitor all relevant scientific literature related to Reglan/metoclopramide.

3.37 Defendants failed to disclose material safety information regarding the serious and permanent side effects caused by taking Reglan/metoclopramide for long periods of time.

3.38 Defendants failed to report data, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of their warnings, efficacy and/or safety of Reglan/metoclopramide.

3.39 Defendants knowingly concealed from physicians material facts bearing on the interpretation of package insert disclosures that exposure to Reglan/metoclopramide can lead to tardive dyskinesia and other extrapyramidal side effects, and that that this risk increases with duration of therapy and cumulative dose.

3.40 Defendants concealed the fact that Reglan/metoclopramide is a neuroleptic agent and dopamine antagonist, which can be expected to lead to tardive dyskinesia and other extrapyramidal side effects with approximately the same high frequency, particularly in long

[1] Defendants are required to review all adverse drug experience information obtained or otherwise received . . . from any source . . . including derived from postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports from the scientific literature, and unpublished scientific reports. 21 C.F.R. § 317.80(b).

term use, as other neuroleptic drugs, and that epidemiological studies have consistently confirmed this expectation.

3.41 Defendants also concealed the fact that the treatment of chronic or intermittent gastroesophageal reflux and/or diabetic gastroparesis and/or other gastric disorders with Reglan/metoclopramide for longer than 12 weeks is unlikely to be reasonably safe.

3.42 Some or all of the Defendants, as a result of their participation as defendants in previous litigation concerning Reglan/metoclopramide products received clear notice of the suppression of important safety information concerning Reglan/metoclopramide, yet despite this notice chose to ignore the information and join consciously in the suppression.

3.43 Under the FDA scheme, Wyeth, Schwarz and Alaven are/were the Reference Listed Drug Company ("RLD"), under a specific New Drug Application ("NDA") for Reglan/metoclopramide.

3.44 At all times material hereto, Wyeth, Schwarz, and Alaven, as the NDA Holder and/or the RLD companies for Reglan/metoclopramide, were aware of the serious side effects caused by Reglan/metoclopramide including, but not limited to, central nervous system disorders, depression with suicidal ideation, akathisia, tardive dyskinesia, tardive dyskinesia, visual disturbances and interference with drug metabolism.

3.45 Defendants Wyeth, Schwarz, and Alaven knew or should have known that generic drug manufacturers customarily copy verbatim the package insert for the name brand prescription drug product and disseminate this information with their products.

3.46 Defendants Wyeth, Schwarz and Alaven knew or should have known that the generic drug manufacturers also typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

3.47 Defendants Wyeth, Schwarz, and Alaven knew or should have known that physicians commonly consult the information disseminated by the name brand manufacturer, in the PDR or otherwise, and rely upon that information in their decisions concerning the prescribing of those products for their patients.

3.48 Defendants Wyeth, Schwarz, and Alaven knew or should have known, specifically, that physicians would rely upon the information disseminated to them by the name brand manufacturer, regardless of whether the prescriptions might be filled with either the name brand product, Reglan, or generic Reglan/metoclopramide, and that many patients, in accordance with those prescriptions, would be likely to ingest generic Reglan/metoclopramide.

3.49 Under the FDA scheme, Defendants Teva Pharmaceuticals USA, Inc. and Qualitest held Abbreviated New Drug Applications ("ANDAs") for Reglan/Metoclopramide.

3.50 Defendants Teva and Qualitest submitted an Abbreviated New Drug Application (ANDA) to the FDA, based on representations made by the RLD companies, requesting permission to manufacture, market, and distribute generic Reglan/metoclopramide.

3.51 Under the ANDA process, the Code of Federal Regulations *required* Teva and Qualitest to submit labels for Reglan/metoclopramide initially identical in all material aspects to the reference listed drug label.

3.52 Under the Code of Federal Regulations, Teva and Qualitest had a duty to ensure their Reglan/metoclopramide warnings to the medical community were accurate and adequate, to conduct post market safety surveillance, to review all adverse drug event information, and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan/metoclopramide.

3.53 Under the Code of Federal Regulations, if Teva and Qualitest discover

information in the course of the fulfillment of their duties as outlined above, they must report that information to the medical community, Plaintiff and other foreseeable users of Reglan/metoclopramide to ensure that their warnings are continually accurate and adequate.

3.54 Defendants Teva and Qualitest failed to investigate the accuracy of their metoclopramide and/or metoclopramide HCl drug labels.

3.55 Defendants Teva and Qualitest failed to review the medical literature for metoclopramide and/or metoclopramide HCl .

3.56 Defendants Teva and Qualitest failed to communicate the true and accurate risks and/or prevalence of severe neurological side effects resulting from the ingestion of drugs containing Reglan/metoclopramide.

4. CLAIMS FOR RELIEF

A. The Louisiana Products Liability Act

4.01 Defendants Teva and Qualitest are liable as the manufacturers, distributors and/or sellers of the drug Reglan/metoclopramide in violation of the Louisiana Products Liability Act, La. R.S. 0:2800.51, *et seq.* ("the LPLA").

4.02 The Reglan/metoclopramide manufactured by Teva and Qualitest was unreasonably defective in design as provided by La. R.S. 9:2800.56 , in that when it left the control of Defendants and/or their representatives, the foreseeable risks of serious harm posed by the drug far outweighed its alleged benefits. In fact, the foreseeable risks were so great that Plaintiff, had she known of such risks, would not have ingested Reglan/metoclopramide.

4.03 The Reglan/metoclopramide manufactured by Teva and Qualitest was unreasonably dangerous due to an inadequate warning as provided in La. R.S. 9:2800.57 in that reasonable care was not utilized to ensure that consumers were adequately warned of the true

characteristics of the product which were likely to cause damage.

4.04 The Reglan/metoclopramide manufactured by Teva and Qualitest was unreasonably dangerous because it did not conform to an express warranty of the manufacturer about the product as provided in La. R.S. 9:2800.58.

4.05 Reglan/metoclopramide was placed into the stream of commerce by Teva and Qualitest acting through authorized agents, servants, employees and/or representatives. Plaintiff was prescribed Reglan/metoclopramide by her physicians and used Reglan/metoclopramide in a manner foreseeable by Defendants.

4.06 The Reglan/metoclopramide ingested by Plaintiff was expected to and did reach Plaintiff without substantial change in its condition as tested, manufactured, designed, labeled, packaged, marketed, and distributed. As a result of the use of Reglan/metoclopramide, Plaintiff suffered serious, permanent and disabling neurological injuries, including, but not limited to, injuries associated with the central nervous and extrapyramidal motor systems, specifically tardive dyskinesia.

4.07 Reglan/metoclopramide was marketed to physicians to be prescribed to their patients and was marketed and advertised directly to the consuming public. Reglan/metoclopramide, as manufactured and supplied to healthcare professionals and the general public, was unaccompanied by proper warnings regarding the serious risks associated with ingestion of the drug. Further, Teva and Qualitest failed to warn of these serious risks after receiving knowledge of the same. The information provided to consumers did not reflect Teva and Qualitest's knowledge that Reglan/metoclopramide was not safe and effective as indicated in its marketing campaign, nor were consumers such as Plaintiff made aware that ingesting Reglan/metoclopramide could result in serious, permanent and disabling neurological injuries

including, but not limited to, injuries of or associated with the central nervous and extrapyramidal motor systems, specifically tardive dyskinesia. Full and proper warnings that accurately and fully reflected the unreasonable risk of central nervous system side effects, depression, akathisia, akinesia, tardive dyskinesia, tardive dystonia, visual disturbances and/or interference with drug metabolism due to the ingestion of Reglan/metoclopramide should have been disclosed by Teva and Qualitest.

B. Unfair Trade Practices

4.08 Defendants Wyeth, Schwarz, and Alaven (hereinafter sometimes referred to as "branded defendants"), through their agents, servants, employees and/or representatives, employed deception, fraud, false pretense, false promise, misrepresentation, unfair trade practices, and the concealment, suppression, and omission of material facts in connection with the sale or advertisement of Reglan/metoclopramide, in violation of the Louisiana Unfair Trade Practices and Consumer Protection Law, La. R.S. 51:1401, et seq. ("LUTPA").

4.09 Defendants' Wyeth, Schwarz and Alaven offer for sale of a consumer product, namely Reglan/metoclopramide, in trade or commerce, constitutes a representation that the product is reasonably safe for its intended purpose and intended use.

4.10 Defendants Wyeth, Schwarz and Alaven, have engaged in deceptive acts or practices, in violation of LUTPA, by knowingly, intentionally and/or recklessly omitting, concealing, and/or suppressing its own data from investigations and clinical trials, other analyses, studies, tests, understandings, and conclusions about the true efficacy and safety of Reglan/metoclopramide.

4.11 Defendants Wyeth, Schwarz, and Alaven; violated LUTPA by intentionally omitting, concealing and/or suppressing, or otherwise failing to communicate and notify the

medical community, the Plaintiff, and other consumers of Reglan/metoclopramide, of the negative safety information they possessed.

4.12 Defendants Wyeth, Schwarz, and Alaven made material misrepresentations that were false and that were either known to be false when made or were asserted without knowledge of their truth. Defendants possessed adverse drug event reports, drug studies, and other documentation about Reglan/metoclopramide, yet made numerous misrepresentations regarding the frequency of related adverse occurrences in their package insert or Physician's Desk Reference label as to the existence, occurrences, and frequency of occurrences, as well as the severity and extent of the overall risk of use of the drug; as to the efficacy of the drugs; as to the number of adverse events with use; and the seriousness and severity of adverse events reported with the use of Reglan/metoclopramide.

C. Breach of Warranties

4.13 Defendants Wyeth, Schwarz, and Alaven were at the time of the acts forming the basis of this lawsuit, and now are, merchants with respect to the Reglan/metoclopramide at issue in this lawsuit. These Defendants marketed and promoted their Reglan/metoclopramide as safe and effective for its intended uses. The Reglan/metoclopramide consumed by Mrs. Johnson reached her without substantial change in its condition and was used by her as intended by Defendants. Defendants expressly and impliedly warranted that the Reglan/metoclopramide was not unreasonably dangerous and instead was merchantable and fit for its intended use by Mrs. Johnson.

4.14 Defendants Wyeth, Schwarz, and Alaven, breached these warranties (both express and implied) as the Reglan/metoclopramide was not merchantable, was unfit for its intended use and was unreasonably dangerous when comparing the benefits to the risks

associated with its use. Plaintiffs were injured as a result of these breaches of warranties.

D. Misrepresentation and Fraud

4.15 Defendants Wyeth, Schwarz, and Alaven; through their advertising, labeling, marketing, and sales/detail persons, made significant representations, which were false, knowing that such representations were false and/or with reckless disregard for the truth or falsity of such representations, with the intent that Plaintiff rely on such material representations; Plaintiff acted in actual and justifiable reliance on such material misrepresentations and Mrs. Johnson was injured as a result.

4.16 In addition, and in the alternative if necessary, Defendants Wyeth, Schwarz, and Alaven knowingly omitted and downplayed material information, which omission constitutes a positive misrepresentation of material facts, with the intent that Plaintiff relied on Defendants' misrepresentations; Plaintiff acted in actual and justifiable reliance on Defendants' representations and Mrs. Johnson was injured as a result.

4.17 Branded defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the Reglan/metoclopramide at issue in this lawsuit, said breach or breaches constituting fraud because of their propensity to deceive others or constitute an injury to public interests or public policy.

4.18 Branded Defendants misrepresented to the FDA, Plaintiffs, and the health care industry the safety and effectiveness of Reglan/metoclopramide and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Reglan/metoclopramide.

4.19 Branded Defendants made these misrepresentations and actively concealed adverse information at a time when they knew, or should have known, that

Reglan/metoclopramide had defects, dangers, and characteristics that were other than what they had represented to Plaintiff and the health care industry generally. Specifically, Defendants misrepresented to and/or actively concealed from Plaintiff and the consuming public that:

a. Reglan/metoclopramide had statistically significant increases in neuromuscular side effects which could result in serious injury;

b. Patients on Reglan/metoclopramide should not take it more than 12 weeks;

c. Reglan/metoclopramide was not fully and adequately tested for the neuromuscular side effects.

4.20 As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Branded Defendants, Plaintiff suffered significant and ongoing injuries and damages.

5. DAMAGES

As a producing and proximate result of the above-described acts and omissions of Teva Qualitest Wyeth, Schwarz, and Alaven; Plaintiff has incurred actual damages in excess of $75,000.00:

(1) Reasonable and necessary medical expenses incurred in the past;

(2) Reasonable and necessary medical expenses reasonably likely to be incurred in the future;

(3) Conscious physical pain and suffering experienced in the past;

(4) Conscious physical pain and suffering reasonably likely to be experienced in the future;

(5) Mental anguish in the past;

(6) Mental anguish likely to be experienced in the future;

(7) Physical disfigurement in the past;

(8) Physical disfigurement likely to be experienced in the future;

(9) Physical impairment in the past;

(10) Physical impairment likely to be experienced in the future;

(11) Loss of earnings/earning capacity likely to be experienced in the future;

(12) Pre and post-judgment interest at the lawful rate; and

(13) Such other applicable damages as the Court deems appropriate.

6. PRAYER

WHEREFORE, Plaintiff TINA JOHNSON prays that upon final determination of these causes of action Plaintiff receive a judgment against Defendants Teva Pharmaceuticals USA, Inc. Qualitest, Wyeth, Schwarz, and Alaven as follows:

(a) Actual damages as alleged, jointly and/or severally against Defendants, in excess of $75,000.00;

(b) Costs of court and reasonable attorney fees necessary for preparation of this case for trial;

(c) Prejudgment interest at the highest lawful rate allowed by law;

(d) Interest on the judgment at the highest legal rate from the date of judgment until collected; and

(e) All such other and further relief at law and in equity to which Plaintiff may show themselves to be justly entitled.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Respectfully submitted,

s/ Terrence J. Donahue, Jr._____
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